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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,719	03/29/2001	Kathleen A. Donovan	07039-260001	4609

7590                  06/18/2002

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HILL, MYRON G

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/821,719	DONOVAN ET AL.
Examiner	Art Unit	
Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 April 2002.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1- 5, 7-10, 15, and 28 is/are pending in the application.

4a) Of the above claim(s) 11- 4 and 16- 27 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1- 5, 7- 15, and 28 is/are rejected.

7) Claim(s) 5, and 8- 10 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

The Group and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1- 10, and 15 (with response claims 1- 5, 7- 10, and 15 plus new claim 28, claim 6 was canceled) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that 17- 22 and 23- 27 are each broken into 5 groups and all drawn to inhibitors of IL-1 beta and it would not be a burden to search. This is not found persuasive because these are drawn to different methods than elected group I and the search for the method of group I is not coextensive for the search for the other methods.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11- 14, and 16- 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1- 5, 7, 15, and 28 are being treated on the merits (see claim objections below).

***Claim Objections***

Claims 5, 8, and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend from themselves. The claims will be treated in this office action as if: claim 5 depends from claim 4 and claim 10 depends from claim 9, and for claims 8 and 10, see the following paragraph.

Claims 8, 9, and 10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is not clear what the basis of the correlation is between IL-1 beta and IL-6 is and it is not clear what the conclusion of the method is. The term "elevated" in claims 3 and 4 is a relative term that renders the claim indefinite. The term "elevated" is not defined by the claim, the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what level is to give a likelihood that correlates with "indicative of" or "likely to progress" to disease state. In claims 3, 4, and 7 what is the metes and bounds of the certainty of the diagnosis or determining the likelihood of progression to disease? Are there false positives or false negatives? In claim 15 is not clear what the "known standard or a patient determined standard" is and the method is not complete because there is no conclusion that indicates what monitoring the status indicates or what causes the change in status.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter (1990 British Journal of Haematology 74: 424- 431, in IDS).

Carter teaches that there is dose dependent correlation between IL-1 beta and the amount of IL-6 produced (figure 1 and page 430, second full paragraph). Carter also teaches that myeloma cells cultured with stromal cells produced IL-6 and this IL-6 production could be blocked by addition of anti IL-1 beta antibodies (Table III).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 15, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter and Klein (1989 Blood Vol 73, No 2, pages 517- 526).  
Carter teaches that there is dose dependent correlation between IL-1 beta and the amount of IL-6 produced (figure 1 and page 430, second full paragraph). Carter also teaches that myeloma cells cultured with stromal cells produced IL-6 and this IL-6 production could be blocked by addition of anti IL-1 beta antibodies (Table III).

Carter does not teach correlation of IL-6 to disease state.

Klein teaches that "bone marrows from patients inactive/slightly active myeloma could be distinguished from those patients with fulminating disease on the basis of IL-6 levels" (page 519 column 2) and shows the measurement of IL-6 of individuals in different disease states in Figure 1.

It would have been obvious to one skilled in the art would have been motivated to measure the level of IL-6 in a myeloma cell- stromal cell co-culture of Carter to determine the status of an individual or monitor the status of an individual as shown by Klein. One skilled in the art would have been able to assay for the amount of cytokine in

a sample and determine the status of a patient or monitor the status of a patient for change.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art to assay a culture and determine the amount of cytokine produced to monitor or assay for a disease state with a reasonable expectation of success.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
June 16, 2002

  
JAMES C. HOUSEL 6/17/02  
SUPERVISORY PATENT EXAMINER  
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